Remarks

This is in response to the Office Action dated June 14, 2006.

With regard to item 1 in the Office Action, note that reference GB2227941 only concerns a possible construction of an adjustable flange. Since none of the claims of the present application mention an adjustable flange, it is believed that the '941 reference is not material to the patentability of the claims and therefore not necessary to be mentioned in an IDS.

With regard to item 2 of the Office Action, the examiner has set forth some objections to the drawings under 37 CFR 1.83(a). The examiner's attention is respectfully directed to the "tracheostomy tube" being shown in Fig. 1 as element "3", and that the "two side openings" are in fact shown in Fig. 4 by designation "214", which, since they are side openings, the opening 214 on the backside of the drawing of Fig. 3 indeed must also be shown. Please refer also to the second paragraph on page 9 of the specification. The objection to the drawings therefore is believed not to be warranted and should be withdrawn.

The examiner has rejected claims 15-17 as being anticipated by Sauer (6,109,264) under 35 USC 102(b). Moreover, Sauer is used in combination with Fortune (US 5,507,279) for rejecting as obvious under 35 USC 103 the subject matter of claims 1-3, 5-11 and 13-14. The combination of Sauer and Fortune is further combined with secondary references Toye (US 6,382,209) and Yoon (US 5,423,760) for rejecting as obvious claims 4 and 12, respectively, under 35 USC 103.

Per the above amendment, claims 1, 3-5 and 13 have been amended; and claims 2, 14-15 canceled.

The pending claims are all directed at devices used to insert a tracheostomy tube through neck tissue into the trachea in the manner of a tracheostomy. In this respect, the

claims have been amended to specify that the needle supports a tubular member in a removable manner such that the needle can be removed from within the tubular member when an indication is given that the trachea has been penetrated.

Many arrangements have been proposed in the past for inserting tracheostomy tubes in emergency situations but these have suffered from a number of problems. One problem is the risk that the insertion instrument will be inserted too far and cause damage to the posterior wall of the trachea. On the other hand, if the clinician is too cautious he may not make the insertion deep enough and this may prevent correct positioning of the tube. Another problem with previous arrangements is the number of different steps and separate devices involved before an adequate airway is provided. The complexity of such arrangements causes delay and may lead to incorrect techniques, especially with inexperienced users working under stress in emergency situations.

The arrangement of the present invention has a spring-loaded member extending along the inside of a needle and coupled at its rear end to an indicator by which movement of the internal member is indicated. This gives a clear indication of initial entry into the trachea and of contact with the posterior wall, if inserted too far. This enables the user to have a high confidence in his ability to use the instrument correctly with a low risk of danger to the patient. Because the needle carries a tubular member ready-assembled on it, it enables an airway to be provided rapidly and easily without the need for additional, separate components or procedural steps.

None of the cited documents disclose a similar arrangement.

Sauer (US6109264) describes a device for forming a tracheostomy. The device has a needle 41 and a guidewire 31 extending along the needle. The needle is pushed through neck tissue to penetrate the trachea and correct placement is detected by testing for resistance to aspiration using an aspiration bulb (see column 10, lines 20 to 25). The guidewire can subsequently be manipulated manually using a thumb ring fitting 29 to

confirm correct placement (see column 10, lines 32 to 47). There is nothing in this document to suggest that the needle include an inner member urged resiliently forwardly so that it moves forwardly when the trachea is penetrated, in the manner of the present invention.

Fortune (US5507279) describes a technique for retrograde insertion of an endotracheal tube. It is, therefore, concerned with a technique for ventilation via the mouth rather than through an opening made surgically in neck tissue. The technique described in the cited document employs a needle having a spring-loaded stem along which a guide wire is inserted into the trachea and up to the mouth. The technique employs a syringe connected to the needle hub to detect penetration of the trachea (column 6 lines 1 to 5). There is no mention in this document that the hub of the needle be transparent or that any visual indication be provided although it is possible that the lever 44 might give some indication. It is clear, however, that the main indication of penetration is provided by the syringe and that the stem 24 serves a safety function of preventing damage should the device be inserted too far. The main distinction, however, between the arrangement described by Fortune and that required by the amended claims of the present application is that the device of the present invention carries a tubular member on its outside, which remains in place to provide ventilation to the trachea after removal of the needle. The device described by Fortune, by contrast, is used for inserting a guide wire after the trachea has been penetrated. There is no suggestion in Fortune that the needle should carry a tubular member on its outside in the manner of the present invention. Given that the Fortune device is concerned with patient ventilation but achieves this by a very different means, it would be a radical departure from the teaching of Fortune to move completely from the retrograde procedure with which the document is concerned and insert a breathing tube directly on the needle device instead of using the endotracheal tube described by Fortune.

Given their respective differences as noted above, it is respectfully submitted that a person skilled in the art would not have combined Sauer and Fortune as suggested in the Office Action. Moreover, even were Sauer to be combined with Fortune as suggested in the

Office Action, such combination nonetheless would fall short of teaching the claimed invention.

Toye (US6382209) describes an arrangement for performing a tracheostomy but, again, this is very different from that proposed by the present invention. Toye has a needle and employs a syringe connected to the rear end of the needle to confirm correct placement by aspiration, in the conventional manner (column 4, lines 2 to 4). After insertion of the needle, the leader of a dilator is inserted manually along the bore of the needle and the needle is then split around the dilator to allow it to be inserted. There is no suggestion by Toye either that insertion be detected in response to movement of a member urged resiliently along the inside of the needle, or that the needle itself carry a tubular member on its outside in the manner of the present invention.

Yoon (US5423760) describes various different forms of safety device some of which have a needle that can be retracted within an outer sleeve. The arrangement of Figures 19 and 20 is an instrument, for an anatomical cavity, with a blunt safety probe 765 that projects from the forward end of a needle. There is no suggestion by Yoon that this instrument would be suitable for penetrating neck tissue over the trachea or that it removably support a tracheostomy tube in the manner now required by the amended claims of the present application.

In view of the foregoing, applicant respectfully submits that the claimed invention is patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,

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Date: Sept 12, 2006